# DOXYLAMINE SUCCINATE AND PHENYLEPHRINE HYDROCHLORIDE- doxylamine succinate and phenylephrine hydrochloride tablet Westminster Pharmaceuticals, LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

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#### **Doxylamine Succinate and Phenylephrine HCl**

#### **DRUG FACTS**

Active ingredients (in each tablet)	Purpose
Doxylamine Succinate 7.5mg	Antihistamine
Phenylephrine HCl 10mg	Nasal Decongestant

#### Uses

Temporarily relieves these symptoms due to the common cold, hay fever (allergic rhinitis) or other upper respiratory allergies:

- nasal congestion
- runny nose
- sneezing
- itching of the nose or throat
- itchy, watery eyes
- reduces swelling of nasal passages

#### **Warnings**

#### Do not exceed recommended dosage.

#### Do not use this product

• if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

#### Ask a doctor before use if you have

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- glaucoma
- trouble urinating due to enlargement of the prostate gland
- a breathing problem such as emphysema or chronic bronchitis

### Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers.

#### When using this product

- exctability may occur, especially in children
- may cause marked drowsiness
- avoid alcoholic drinks
- alcohol, sedatives and tranquilizers may increase the drowsiness effect

use caution when driving a motor vehicle or operating machinery

#### Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- symptoms do not improve within 7 days or are accompanied by fever

**If pregnant or breast-feeding,** ask a health professional before use.

#### Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away.

#### **Directions**

#### Do not exceed recommended dosage.

Adults and children 12 years	1 tablet every 4 hours, not to exceed 6 tablets
of age and over:	in 24 hours.
Children 6 to 12 years of age:	1/2 tablet every 4 hours, not to exceed 3 tablets in 24 hours.
Children 6 years of age and under:	Consult a physician.

#### Other Information

Store at 15°-30°C (59°-86°F)

Supplied in a tight, light-resistant container with a child-resistant cap. Doxylamine Succinate and Phenylephrine HCl tablets are light blue, caplet shaped, scored tablets, debossed "WP" bisect "199" on one side and plain on the other.

#### **Inactive ingredients**

FD&C Blue #2 Aluminum Lake, Magnesium Stearate, Microcrystalline Cellulose, Silicone Dioxide, Sodium Starch Glycolate

#### **Questions? Comments?**

Call 1-844-221-7294

#### PRINCIPAL DISPLAY PANEL - 100 Tablet Bottle Label

NDC 69367-199-01

Doxylamine Succinate and Phenylephrine HCl

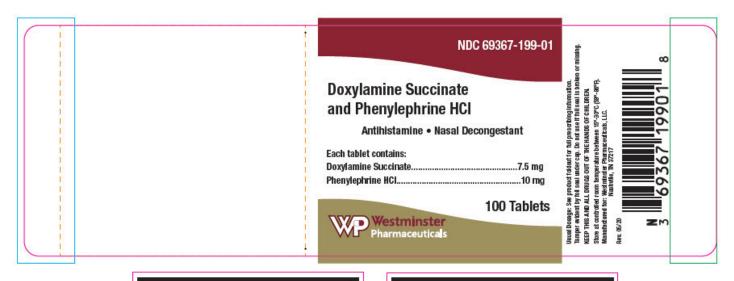
Antihistamine • Nasal Decongestant

Each tablet contains:

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Phenylephrine HCl

10 mg



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DRUG FACTS (continued)

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Manufactured for:

Westminster Pharmaceuticals, LLC. Nashville, TN 37217

Rev. 05/20

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#### DOXYLAMINE SUCCINATE AND PHENYLEPHRINE HYDROCHLORIDE

doxylamine succinate and phenylephrine hydrochloride tablet

#### **Product Information**

HUMAN OTC DRUG NDC:69367-199 Product Type Item Code (Source)

Route	of Administration	ORAL
wut	or manning a audi	Olule

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
<b>DOXYLAMINE SUCCINATE</b> (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	7.5 mg	
PHENYLEPHRINE HYDRO CHLO RIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg	

Inactive Ingredients			
Ingredient Name	Strength		
FD&C BLUE NO. 2ALUMINUM LAKE (UNII: 4AQJ3LG584)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)			
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)			
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)			

Product Characteristics			
Color	BLUE	Score	2 pieces
Shape	OVAL	Size	14mm
Flavor		Imprint Code	WP;199
Contains			

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:69367-199- 01	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/25/2018	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	10/25/2018	

## Labeler - Westminster Pharmaceuticals, LLC (079516651)